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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,376	07/02/2001	Frank D. Hong	UTSC:645US/SLH	2755

7590 09/23/2002

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EXAMINER
YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
1642	9

DATE MAILED: 09/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/899,376	Applicant(s) HONG ET AL.	
	Examiner Christopher H Yaen	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-85* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 7-15, drawn to peptide and a composition comprising a drug and a peptide, classified in class 530, subclass 300.

II. Claims 4-6, drawn to a DNA segment, classified in class 536, subclass 23.1.

III. Claims 16-26, 51-63, and 84-85, drawn to a method of killing a tumor cell with a peptide composition, classified in class 514, subclass 2.

IV. Claims 27-32 and 82-83, drawn to a method of detecting cancer with a peptide *in vivo*, classified in class 514, subclass 2.

V. Claims 33-36, drawn to a method of detecting cancer with a peptide *in vitro*, classified in class 514, subclass 2.

VI. Claims 37-50, 64-67, drawn to a kit for detecting and imaging cancer, classified in class 530, subclass 402.

VII. Claims 68-72, drawn to a composition comprising a peptide and a nucleic acid, classified in class 530, subclass 402.

VIII. Claims 73-77, drawn to a method of treating an organism for cancer, classified in class 514, subclass 2.

IX. Claims 78-81, drawn to a method of isolating a peptide, classified in class 530, subclass 412.

The inventions are distinct, each from the other because of the following reasons:

2. The inventions of groups I-II and VI-VII differ one from the other because they have different structural , chemical , and functional properties that can be used for distinct purposes and have different effects.

3. The inventions of group III-V and VIII-IX differ one from the other because they are drawn to methodological steps that have different purposes, outcomes, effects and have different protocols for which to use for different reasons.

4. Inventions I,VI-VII and III-V, VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of the different groups can be used with materially distinct products that can achieve the same effect, such as through chemical compounds or through other patentable distinct protein or peptide compositions.

5. Inventions IX and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the peptide of group I can be made through artificial means such as through recombinant product or through an peptide synthesizer.

6. The inventions of group II and III-V, VIII-IX are unrelated because the method of groups III-V, VIII-IX require the use of proteins or peptide compositions while the invention of group II is a nucleic acid molecule or DNA segment.

7. Because these inventions are distinct for the reasons given above and the search required for the different groups are not required for any of the other groups, and because they require a search of different databases which are unrelated and non-coextensive, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. If the applicant elects group III, please select one of the following species:

i. Tumor cell types (claim 19): squamous cell carcinoma, head and neck cancer, and breast cancer;

ii. Gene therapy nucleic acid sequences (claim 63): *ras, myc, raf, erb, src,fms,jun,trk, ret, gsp, hst,bcl,abl,*Rb,CFTR,p16,p21,p27,p53,p73,C-CAM, APC, CTS-1,zac-1,scFV, DCC, NF-1, NF-2, WT-1, MEN-I, MEN-II, BRCA1, VHL, MNAC1, FCC, MCC, BRCA2, IL-1, IL-2, IL-3, IL-5, IL-6,IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, GMCSF,GCSF, and thymidine kinase.

b. If applicant elects group VII, please select one of the following species:

i. Gene therapy nucleic acid sequences (claim 72): *ras, myc, raf, erb, src,fms,jun,trk, ret, gsp, hst,bcl,abl,*Rb,CFTR,p16,p21,p27,p53,p73,C-CAM, APC, CTS-1,zac-1,scFV, DCC, NF-1, NF-2, WT-1, MEN-I, MEN-II,

BRCA1, VHL, MNAC1, FCC, MCC, BRCA2, IL-1, IL-2, IL-3, IL-5, IL-6,IL-7, IL-8, IL-9, IL-10, IL-11, IL-12, GMCSF,GCSF, and thymidine kinase.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 19, 63, and 72 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. Because of the complexity of the restriction requirement, a telephonic election was not made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
September 12, 2002

BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600